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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/980,614	04/17/2002	Yi Li	900163.401USPC	8325

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EXAMINER
AZPURU, CARLOS A

ART UNIT	PAPER NUMBER
1615	

MAIL DATE	DELIVERY MODE
01/15/2008	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	09/980,614	LI ET AL.	
	Examiner	Art Unit	
	Carlos A. Azpuru	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 October 2007.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-16 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-14 is/are rejected.
- 7) ☒ Claim(s) 15 and 16 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
 Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
 Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date _____ | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Receipt is acknowledged of the amendment filed 10/15/2007.

The following rejection is maintained in this action:

Claim Rejections - 35 USC § 103

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

Azizi et al disclose transplantation of human marrow stromal cells and astrocyte precursors (neurospheres) (see Abstract; page 3910, Results). The transplanted cells behaved like endogenous CNS stem cells (see Migration of Implanted Cells, page 3911). Finally, Azizi et al suggest the use of the transplant in the treatment of various disease. Azizi et al teaches the administration of the same cells, by the same route, to the same organ, and said cells migrate in the same way as claimed in the instant application. Azizi et al further provide the suggestion to use said implants in the treatment of various CNS diseases. While Azizi et al does indeed use a healthy brain, the mechanism of action of these migrated cells is an inherent property of these cells, not the condition of the brain. They would function in the same way regardless of the condition of the brain. Further, while applicant adds the term "penumbral", this term merely refers to adjacent portions of the CNS as disclosed by Azizi et al. There is no specific "penumbral tissue" of the brain which differentiates the instant claims from the

generic disclosure of Azizi et al to transplant these cells into CNS tissue, and for the same therapeutic purpose. Azizi et al does indeed show, survival, engraftment, and migration of these stromal cells. While Azizi et al also deliver their cells to a healthy CNS, there is no showing that delivery to damaged or diseased tissue would function any differently. Further, there is a clear suggestion to treat CNS diseases by Azizi et al. It is agreed that Azizi et al do not teach that the transplanted cells would differentiate into parenchymal cells in the brain. However, the evidence presented by the Azizi et al paper indicates that these transplanted cells do indeed become differentiated once they are transplanted given that they are said to behave like endogenous CNS cells. The process of differentiation of these cells is therefore expected once the cells are isolated, transplanted and migration takes place. Indeed, this migration appears to be evidence of differentiation. Therefore, barring a showing that tis transplantation would behave differently in healthy vs damaged central nervous tissue, those of ordinary skill would have expected similar therapeutic results from the transplantation of cells as disclosed by Azizi et al. The instant claims would have been obvious to one of ordinary skill in the art at the time of invention given the disclosure of Azizi et al.

Response to Arguments

Applicant's arguments filed 10/15/2007 have been fully considered but they are not persuasive.

Applicant argues that the Azizi et al reference does not teach each element of the claimed invention. In particular, applicants point out that the reference lacks a teaching of activating the differentiation of endogenous neural cells by transplanting bone marrow cells into the central nervous system. However, it is noted that claim 3 does not recite this claimed limitation, and only refers to the transplantation of bone marrow cells taught by Azizi et al.

Further, it must be noted that Azizi et al discloses the transplantation of the same cells, by the same methods, to achieve the same end results, Administration is within the central nervous system. While the subsequent differentiation of the endogenous cells may be a newly discovered result of this administration, there is no reason to expect different results from those suggested by Azizi et al. While applicant argues that specific areas are not indicated for transplantation by Azizi et al (areas adjacent to injured or impaired tissue or an ischemic boundary zone), Azizi et al includes the teaching that these cells migrate to the areas they are needed. This clearly indicates that proximity to these regions is not a critical element to the claimed treatment.

Applicant further argues that the reference does not utilize a composite of mesenchymal cells and neurospheres. Azizi et al does however teach the separate administration of mesenchymal cells and astrocyte precursors. While this may not

specifically recite neurospheres, these astrocyte precursors are inclusive of neurospheres. Applicant is inserting limitations into the teachings of Azizi et al, which are unfounded. Clearly, the method's end result is expected to be the same. Barring a showing that astrocyte precursors other than neurospheres would not produce the same result, this argument is not persuasive.

For the reasons cited above, the rejection under 35 USC 103(a) is maintained.

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

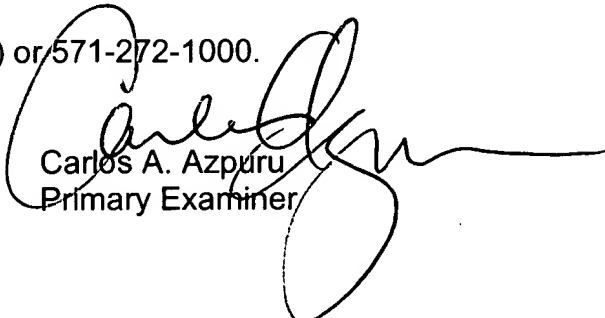
A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Claims 15 and 16 are objected to as dependent upon a rejected base claim.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Carlos A. Azpuru whose telephone number is (571) 272-0588. The examiner can normally be reached on Tu-Fri, 6:30 am - 5:00 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.


Carlos A. Azpuru
Primary Examiner

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